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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/928,048	08/10/2001	Thomas L. Cantor		7860

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EXAMINER

COUNTS, GARY W

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 09/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/928,048

Applicant(s)

CANTOR, THOMAS L.

Examiner

Gary W. Counts

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-9 and 17-25 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-9 and 17-25 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Status of the claims

The Request for Continued Examination filed July 27, 2004 is acknowledged and has been entered.

Restriction Status

In the Amendment filed July 27, 2004, Applicant indicates that the terms "CIP" or "CIP fragment" are the same and are not patentably distinct (see Remarks section under the section entitled Restriction status and therefore, claims 1-6 are regrouped with claims 7-9 and 17-25.

Claim Rejections - 35 USC § 112

1. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

2. Claims 1-9 and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. On page 5, second paragraph, lines 9-14 in the specification. The applicant discloses that in making a direct measurement of CIP, one can use an antibody or antibody fragment specific for a peptide sequence for CIP which by virtue of the unique CIP protein conformation is available for antibody binding but this same epitope is not available for antibody bind in CAP by virtue of the

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unique CAP protein conformation of CAP, in an amount sufficient to behind the CIP present, and thus, enable immunoassay measurement. Applicant's language is prophetic in nature and does not indicate that such a distinguishing antibody has been produced at the time of filing. Applicant does not disclose an antibody that is able to distinguish a peptide sequence for CIP that present an epitope available for antibody binding in CIP, but does not bind to the same peptide sequence in cyclase activating parathyroid hormone. There is no description of an antibody in the specification that distinguishes a peptide sequence for CIP that presents an epitope on CIP and does not bind to CAP.

3. Claims 1-9 and 17-25 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Enablement requires that the specification teach those in the art to make and use the invention without undue experimentation. The factors that must be considered in determining undue experimentation are set forth in *In re Wands* USPTQ2d 14000. Factors to be considered in determining whether a disclosure would require undue experimentation include (1) the nature of the invention, (2) the state of the prior art, (3) the predictability or lack thereof in the art, (4) the amount of direction or guidance present, (5) the presence or absence of working examples, (6) the quantity of experimentation necessary, (7) the relative skill of those in the art, and (8) the breadth of the claims.

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The instant claims are directed to a method for measuring the amount of cyclase inhibiting parathyroid hormone (CIP) fragment in a sample by adding to the sample a first antibody or antibody fragment (or adding to a sample a labeled antibody or antibody fragment) specific for a peptide sequence for cyclase inhibiting parathyroid hormone (CIP), but does not bind to this same peptide sequence in cyclase activating parathyroid hormone.

The disclose fails to teach an antibody that distinguishes a peptide sequence for CIP that present an epitope available for antibody binding in CIP, but does not bind to this same peptide sequence in cyclase activating parathyroid hormone. The instantly recited claims are totally dependent on the ability of the antibody to discriminate between the CIP presenting the epitope and the cyclase activating parathyroid hormone. Further, a search of the art indicates that such an antibody is not well known in the art. Also, applicants own statements in the specification indicate that such an antibody is not known in the art (For instance, on page 5, second paragraph, lines 9-21 in the specification. The applicant discloses that in making a direct measurement of CIP, one can use an antibody or antibody fragment specific for a peptide sequence for CIP which by virtue of the unique CIP protein conformation is available for antibody binding but this same epitope is not available for antibody bind in CAP by virtue of the unique CAP protein conformation of CAP, in an amount sufficient to behind the CIP present, and thus, enable immunoassay measurement. In other words, conformation changes between CAP and CIP do not make the CIP binding site available on CAP. Such a domain has been identified that functions in the opposite manner). Further,

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these antibodies are not well known in the art and thus one of ordinary skill in the art would have a low level of predictability in the art.

There are no working examples providing an antibody which distinguishes a peptide sequence for CIP that present an epitope available for antibody binding in CIP, but does not bind to this same peptide sequence in cyclase activating parathyroid hormone nor are there any working examples to provide guidance.

Because the disclosure fails to teach an antibody which distinguishes a peptide sequence for CIP that present an epitope available for antibody binding in CIP, but does not bind to this same peptide sequence in cyclase activating parathyroid hormone and because the art is unpredictable, such is not seen as sufficient to support the breadth of the claims and one skilled in the art cannot practice the claimed invention without undue experimentation.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 1-9 and 19-25 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is vague and indefinite because it is unclear how the method works without a step for separating bound labeled antibody from unbound labeled antibody. Because without a separation step one would obtain a positive signal whether or not binding had occurred.

Claim 1, line 7 is vague and indefinite because of the use of parenthesis (). It is unclear if the recitation within the parenthesis is part of the claim or not.

Claim 4, the recitation "protein binding surface" is vague and indefinite. It is unclear what applicant is trying to encompass. See also deficiency found in claim 19.

Claim 7 is vague and indefinite because it is unclear how the method will work if the label is on the second antibody. The second antibody does not differentiate between CIP and cyclase activating parathyroid hormone and therefore how could a determination be made that it is binding to only the CIP which is to be measured.

Claim 7, lines 7 & 8 is vague and indefinite because of the use of parenthesis (). It is unclear if the recitation within the parenthesis is part of the claim or not.

Response to Arguments

6. Applicant's arguments with respect to claims 7-9 and 17-25 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gary W. Counts whose telephone number is (571) 2720817. The examiner can normally be reached on M-F 8:00 - 4:30.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on (571) 272-0823. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Gary Counts
Examiner
Art Unit 1641
September 1, 2004



LONG V. LE
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09/06/04